REMARKS

Claims 1-4, 6-10, and 12-21 are pending. The claims have not been further amended and are provided here to complete the record. Applicant respectfully requests reconsideration of the pending claims in view of the remarks provided below.

The Pending Claims are Supported by an Enabling Disclosure

Claims 1-3, 6-9, and 12-21 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing the enablement requirement. Specifically, the Examiner found Applicant's arguments regarding enablement unpersuasive because, "the specification teaches that the synergistic effect for myeloma treatment occurs when are shaped human PM-1 antibody and melphalan are used together." Final Office Action, page 2. Applicant submits that the Examiner has failed to demonstrate that one of ordinary skill in the art would have to engage in undue experimentation to practice the full scope of the claimed invention.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

MPEP 2164.02 provides that, "[t] he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must

evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims." A rejection based solely on the fact the claimed invention is supported by only one Example is not valid. For the present rejection to be valid, the Examiner must provide a reasonable explanation of why the claimed invention does not satisfy the enablement requirement. However, the Examiner provided no such.

On the other hand, as can be seen from the description and Examples in the specification, it is clear that the observed synergistic effect is provided by a combination of (1) inhibition of IL-6 activity by an anti-IL-6 receptor antibody, and (2) melphalan. There is no reasonable basis for one of ordinary skill in the art to conclude that the observed effect disclosed in the specification specifically requires the use of a reshaped human PM-1 antibody. A far more reasonable interpretation of the data disclosed would lead a skilled artisan to conclude that the use of any inhibitory anti-IL-6 receptor antibody and melphalan would provide the same synergistic effect as provided by a combination of a reshaped human PM-l antibody and melphalan because the observed effect results from the inhibition of IL-6 receptor activity.

To reject the claimed invention due to insufficiency of the enablement requirement, the Examiner must provide some support for the opinion that the synergistic effect shown in the Examples was provided by a mechanism or effect different from inhibition of IL-6 activity by an anti-IL-6 receptor antibody. Without such evidence, a person of ordinary skill in the art would reasonably conclude that any anti-IL-6 receptor antibody which inhibits IL-6 activity as the reshaped human PM-1 antibody did, would provide the same effect as provided by the reshaped human PM-l antibody. Therefore, the claimed invention satisfies the enablement requirement.

Terminal Disclaimer

Applicant submits herewith a Terminal Disclaimer over U.S. Patent No. 7,566,453, which is sufficient to overcome the double patenting rejection raised in the final Office Action.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 350292000402. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 6, 2010

Respectfully submitted,

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